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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,403	05/15/2001	Robert Johnson	A1669cip	9139
33197	7590	08/18/2006	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			DAWSON, GLENN K	
4 VENTURE, SUITE 300				
IRVINE, CA 92618			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/855,403	<b>Applicant(s)</b> JOHNSON ET AL.	
	<b>Examiner</b> Glenn K. Dawson	<b>Art Unit</b> 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 13, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 13 is/are allowed.
- 6) ☒ Claim(s) 1-9, 22, 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9,22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 22, there is no antecedent basis for "said air passage".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9,22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide support for the limitation of the mixing chamber being octagonal or the interior walls include wall segments joined at acute angles. The specification indicates that, in cross-section, there might exist the planar segments or the octagonal shape. However, the specification and drawings together are inconsistent. The figures seem to clearly show that the chamber is really formed from two conical portions attached at either end of a central short cylindrical portion. The inside walls and

wall segments would actually be round or curved in orientation, not planar or octagonal. Even though in cross-section these exist, in actuality, the internal walls of the chamber would not appear not contain any planar segments due to the constant curvature of each of the walls. Clarification and correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,7-9,22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gupte, et al.-5676130. Gupte discloses a mouthpiece 8 attached to a spacer chamber of octagonal shape see fig. 6. The chamber has an inlet port attached to an MDI and an air inlet port attached to the mouthpiece. The exhaust port in the mouthpiece is that which the user places in the mouth. Adaptor or coupling 4 would allow to attachment of a nebulizer, if desired as well.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3,4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupte, et al.-'130 in view of Rowland-5782232.

Gupte discloses the invention as claimed with the exception of the flapper valve in the end of the mouthpiece. Rowland discloses such a flapper valve in a mouthpiece wall. It would have been obvious to have provided the mouthpiece of Gupte with a flapper valve in order to allow for any exhaled air to exit the device.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupte, et al. in view of Watt-6578571.

Gupte discloses the invention as claimed with the possible exception of the filter, valve and adaptor. Gupte does disclose an adaptor 4 which as pointed out above could couple to different devices. However, if this is not found persuasive, Watt discloses that it was known to place one-way valves and filters between the various components of a drug delivery device. It would have been obvious to have provided valves and filters on Gupte's device in order to ensure proper flow direction and reduce possible contamination of the parts. To have provided a universal adaptor to Gupte would have been obvious so that the device could attach to various drug delivery devices, as taught by Watt.

Claims 1-9 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watt-6578571 in view of Gupte, et al.-'130.

Watt discloses the invention as claimed with the exception of the shape of the spacer chamber. Additionally it would have been obvious to have made the spacer member 4 of Watt in the claimed shape of an octagon, as Gupte discloses such a shape reduces undesirably-sized particles.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 05-30-2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6363932 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Allowable Subject Matter***

Claims 10 and 13 are allowed

***Response to Arguments***

Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
10 August 2006